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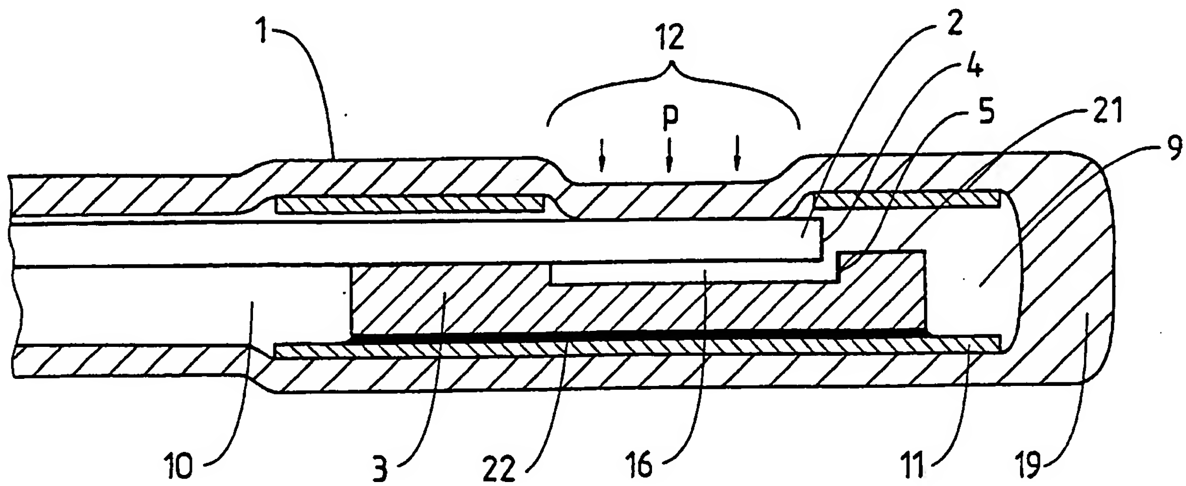

(57) Abstract

Minaturized sensor for physiological pressure measurements in situ, including an elastic sleeve (1) with a diaphragm portion through which the hydrostatic pressure is transmitted as a force acting on a light conductor (2) which is supplied with light from an external source and fixed to a support body (3) such that the hydrostatic pressure variations cause elastic, relative positional variations between the end surface (4) of the light conductor (2) and a light-reflecting surface (5) on the support body (3), which in turn give rise to variations in reflected light intensity transmitted back through the light conductor (2), to serve as a pressure signal.

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MINIATURIZED SENSOR FOR PHYSIOLOGICAL PRESSURE MEASUREMENTS

Pressure measurements in human organs are an important source of information for diagnosing different states of illnesses. In the heart and blood vessel system, pressure measurements give information as to the pumping capacity of the heart, the closing and opening functions of the ventricles, constrictions and deposits in blood vessels, as well as deviations from the normal state in the peripheral network of blood vessels. Pressure measurements can also give valuable diagnostic information when applied to the different parts of the digestive system, from the throat to the anus. The state of urethras, spine as well as uterus is also diagnosed by pressure measurements, as well as several of the liquid filled body cavities such as.

Often both static pressure and dynamic pressure sequences are measured.

Conventional measurement techniques is based on hydraulic pressure transmission in liquid filled catheters between the measurement site and an externally placed pressure indicator. Such a system seldom manages to register pressure vibrations of a higher frequency than some tens of Hertz. The limitation lies with the inertia of the liquid in combination with elastic components, which give rise to resonance phenomena. The properties are seldom completely stable but are drastically effected by such as the presence of microscopic air bubbles.

The problems discussed above can be solved by miniaturized pressure sensors which are applied directly to the measurement site, the measuring signal being transmitted via electrical or optical fibres. A number of examples of such arrangements have been published and these have also resulted in commercially available products (IEEE TRANSACTIONS ON BIO-MEDICAL ENGINEERING. Vol. BME-17, No. 3. p. 207-209, July 3, 1970, "MINIATURIZED PRESSURE TRANSDUCER INTENDED FOR INTRAVASCULAR

USE" by Lars Lindström and DIGEST OF THE 11th INTERNATIONAL CONFERENCE ON MEDICAL AND BIOLOGICAL ENGINEERING - 1976 - OTTAWA, "DEVELOPMENT AND EVALUATION OF FIBER OPTIC PRESSURE CATHETER" by Saito and Masumoto, p. 690, and "30 th ACMB" - LOS ANGELES, November 5-9, 1977, "AN IMPROVED FIBEROPTIC CATHETER FOR INTRAVASCULAR PRESSURE AND SOUND MEASUREMENTS" p. 292 by French and Gerhard). Their clinical use has been extremely limited, however. The reason for this is primarily that the degree of miniaturization has not been sufficient. The commercially available sensors have an outer diameter of from 1.5 mm and upwards. This results in that clinical routines must be departed from, and in some cases a surgical operation will be necessary. Most often, such complications can not be accepted, which has meant that the use of the miniaturized sensors has been very limited. An other important factor is the high price of the sensors, which is partly a consequence o their relatively complex fabrication, with a plurality of complicated elements, the assembly of which has often taken place using manual methods. The absence of functioning calibration routines is a further factor which has limited the spread of the miniaturized sensors.

The present invention provides a solution to these and associated problems, since it relates to the fabrication of a miniaturized pressure sensor which can have an exterior diameter of 0.5 mm. This allows the sensor to be used without needing to depart from established clinical routines. The sensor can be inserted through ordinary injection needles and catheters, even into narrow blood vessels and cavities. The sensor is manufactured with material and methods adapted from semi-conductor technology, which results in low price costs. Manual and manipulative fabrication steps are replaced with the batch production of hundreds of elements at the same time. Furthermore, the small dimensions afford a practical solution to the calibration problems apparent from the Swedish patent 441 725.

The distinguishing features for the pressure sensor in

accordance with the invention are disclosed in the accompanying claims.

A preferred embodiment of the invention will now be described in the following, and in connection with the accompanying drawings, on which

Figure 1 is a principle embodiment of the pressure sensor in accordance with the invention,

Figure 2 illustrates the sensor in a complete measuring system,

Figure 3 is an embodiment of the sensor with a special calibration function, and

Figures 4a and 4b are schematic axial views of parts of the sensor.

The functional principle of the sensor is illustrated in Figure 1. Light from an externally placed instrument unit is passed via a light conductor, optical fibre 2 to the sensor structure itself. The light conductor 2 may be a glass or plastics fibre, with core and cladding of different optical refractive indices in accordance with the state of the art. In the sensor structure, the light conductor 2 is ridigly mounted on a body 3, which has a form enabling the end surface 4 of the light conductor 2 to be placed adjacent a specularly reflecting surface 5 on the body 3. Between the end portion of the light conductor 2 and the body there is a space 16 enabling elastic bending movements of the end portion. Such bending movements are induced by hydrostatic pressure applied to the diaphragm portion of an elastic sleeve 1, this portion being in contact with the flexing end portion of the conductor. The elastic sleeve, made from such as silikone or similar material, is stretched over a catheter tube 11 surrounding the body 3 and the flexing end portion of the conductor 2, thus forming a tight sheath surrounding the

sensor. In the wall of the tube 11 there is an aperture 12 enabling the transfer of force from the diaphragm portion of the sleeve 1 to the flexing end portion of the light conductor 2. The sleeve 1 thus has the form of a surrounding jacket which is closed off at one end, whereby the inner cavity 9 of the sensor is separated from its nearest surroundings. The cavity 9 does have, however, communication with the surrounding air pressure via a venting duct 10. This duct extends parallel to the light conductor 2, which is also used for signal transmission to an instrument unit connected to it. Light from the end surface 4 of the light conductor 2 is reflected at the surface 5 on the body 3, and the reflected light intensity is dependent on the mutual relationship between the end surface 4 and surface 5.

Figure 2 illustrates how the sensor is connected to an exterior instrument unit 8. This connection suitably takes place with the aid of fibre-optical connector 15. The instrument unit 8 includes a light source, e.g. a light emitting diode, a detector, e.g. a photo diode, and a fibre optic branch. In addition, the unit contains an amplifier, control unit and display unit e.g. a printer or chart recording instrument.

The embodiment of the sensor illustrated in Figure 2 is one where the light conductor is in two parts 6 and 7, in order to facilitate manufacture. There is also a vent hole 17 to ensure that the venting duct 10 is in communication with ambient air pressure.

Figure 3 illustrates an embodiment permitting simplified caibration of the sensor. The sensor structure, with the lightwave conductor 2, sleeve 1 and body 3 is extended in the probing direction to include a cavity 14 with elastic walls, suitably manufactured form the same material as, and integral with the sleeve 1. Via a duct 13 the cavity 14 is in communication with an externally placeable pump means, e.g. a hypodermic syringe. The cavity 14 can thus be inflated to

expand and seal against the inner wall of a surrounding catheter. The pressure sensor will thus be accessible for the calibrating pressure applied through this catheter (c.f. Swedish patent 441 725).

Figures 4a and 4b are schematic axial views of the light conductor end 4 and the reflecting surface 5. In Figure 4a the width of the body 3 is greater than the diameter of the light conductor 2, while the opposite is the case in Figure 4b. The hatched areas 18 and 20 represent the increment in reflected light intensity obtained for a given relative positional change between the surfaces 4 and 5. Due to the circular cross section of the light conductor, there is non-linearity in the case depicted in 4a, while the case depicted in 4b gives a substantially linear relationship, and is thus the most favourable of the two in this respect. Several detail implementations are possible to achieve the same effect, e.g. the side edges, vertical in the figures, of the reflecting surface 5 can be chamfered.

The shape of the body 3 can be obtained in several ways. A suitable method is to utilize single-crystal silicon as material. The reflecting surface 5 can then contitute an elementary crystal plane, e.g. the (111)-plane or the (100)-plane, according to Miller's nomenclature for cubic crystal symmetry. In several etching liquids, e.g. potassium hydroxide, the etching rate is lower in both these crystal plane directions compared with those of higher orders. In so-called pattern etching, i.e. etching with a lithographic mask of given pattern, the elementary planes will be formed after the etching liquid has acted for a longer time. The ainistrohy of the etching also causes the resulting surface to have great smoothness and thus good specular reflection. By thin film coating, e.g. with aluminium, the reflection can otherwise be further improved.

In pattern etching the initial material is suitably a large wafer of single-crystal silicon, from which a larger number of

units can be manufactured simultaneously. This enables good manufacturing economy, in spite of the extreme demands on dimensional tolerances and surface finish. Usually, a silicon wafer of a diameter of 5-150 mm and a thickness of 0.2-0.4 mm is used. The crystalline orientation of the wafer is usually such that the flat surfaces are (100)-planes or (110)-planes. These surfaces are allowed to form the three main surfaces 21, 22 of the body. For the etching, the reflecting surface 5 may be a (100)-plane in the former case and in the latter case a (111)-plane. Etching is carried out so that a mask defines the longitudinal extension of the space 16, while the etching time determines the depth of the space. The mask can further define the width of the reflecting surface 5, as well as the width of the entire body 3. The situation is namely that the individual bodies 3 can be broken off from the original wafer if stress concentrations in the form of longitudinal grooves are simultaneously etched together with the space 16. Alternatively, the wafer can be parted into the individual bodies 3 by sawing with a diamond saw.

One skilled in the art will understand that the invention can be varied in many ways within the scope of the accompanying claims.

CLAIMS

1. Miniaturized pressure sensor for physiological pressure measurements in situ, characterized by a sleeve (1) of elastic material, which surrounds the sensor, the sleeve being formed with a diaphragm portion and also having its end (19) in the insertion direction of the sensor closed off; a light conductor (2) fixed to a support body (3) such that the conductor has a projecting end portion freely elastically deflectable in response to a force acting on said end portion in a direction substantially at right angles to the longitudinal direction of the light conductor, its deflection being a monoton function of the force acting on it, said end portion being in contact with the diaphragm portion of the sleeve (1), as well as having its end surface (4) disposed for coaction with a reflection surface (5).

2. Sensor as claimed in claim 1, characterized in that the support body (3) is formed from single-crystal silicon, and that the reflecting surface (5) is formed on the body and comprises an elementary crystal plane, e.g. the (100)-plane or (111)-plane.

3. Sensor as claimed in claim 1 or 2, characterized in that both the reflecting surface (5) and the main surfaces (21, 22) of the body (3) are (100)-planes.

4. Sensor as claimed in claim 1 or 2, characterized in that the reflecting surface (5) is a (111)-plane and the main surface (21, 22) of the body are (110)-planes.

5. Sensor as claimed in claim 1, characterized in that the reflecting surface comprises a thin film of highty reflective material such as aluminium.

6. Sensor as claimed in any one of the preceding claims, charactrized in that the light conductor (2) comprises at least two parts (6, 7) connected together, namely a part (6) in mechanical communication with the flexible diaphragm

portion of the sleeve (1) and a portion (7) constituting an optical fibre intended for transmission of light to and from an instrument unit (8).

7. Sensor as claimed in any one of the preceding claims, characterized in that the sleeve (1) defines an inner, air-filled cavity in the sensor, which is in communication via an air-filled duct (10) with a reference pressure, e.g. the prevailing air pressure.

8. Sensor as claimed in any one of the preceding claims, characterized by a protective tube (11), e.g. off stainless steel, with at least one side aperture (12) enabling the mechanical connection between the membrane portion of the sleeve (1) on the outside of the tube and the light conductor (2) on the inside of the tube.

9. Sensor as claimed in any one of the preceding claims, characterized by at least one tube (13) extending parallel to the light conductor (2), one end of the tube opening out in a chamber (14) having elastic wall material.

10. Sensor as claimed in any one of the preceding claims, characterized by at least one fibre optical connector means (15) for connecting to an apparatus unit (8) is mounted on one end of the light conductor (2) of the optical fibre (7).

11. Sensor as claimed in any one of the preceding claims, characterized in that all the defining surfaces of the support body (3) form right angles.

12. Sensor as claimed i any one of the preceding claims, characterized in that the end surfaces (4) of the light conductor (2) is circular, and in that the reflecting surface (5) has a width, i.e. a dimension in a direction at right angles to the direction in which the end surface (4) moves in response to the pressure alterantions, which is less than the diameter of the end surface (4).

Fig 1

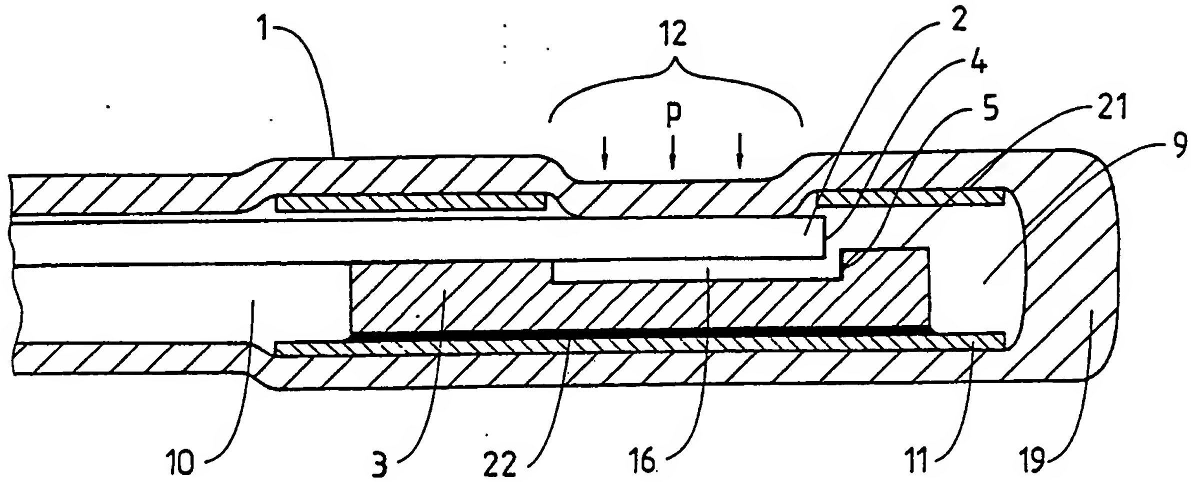


Fig 2

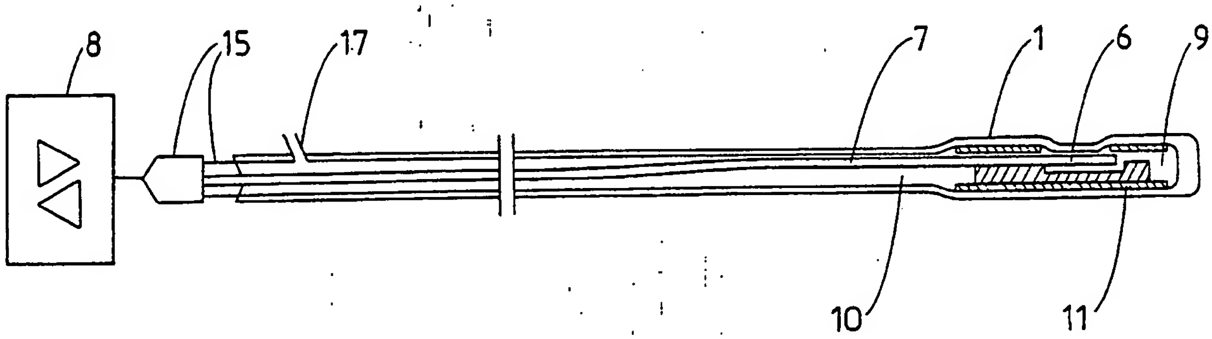


Fig 3

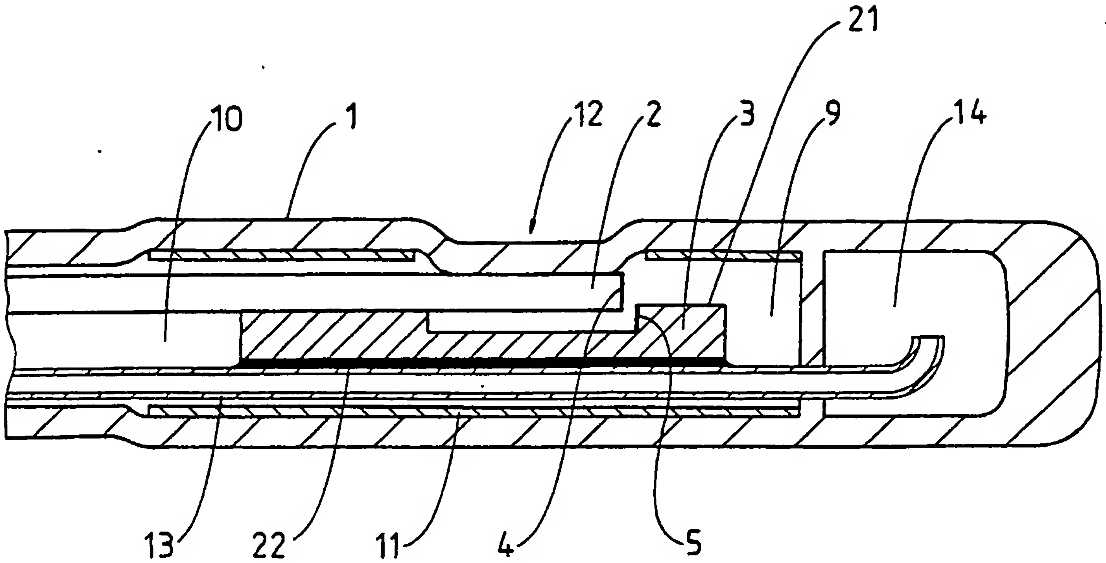
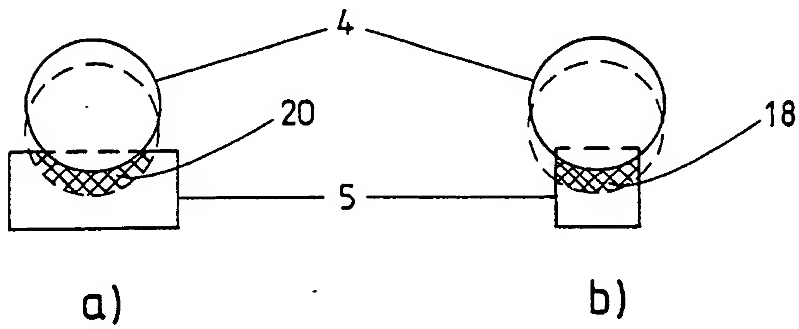


Fig 4



INTERNATIONAL SEARCH REPORT

International Application No. PCT/SE87/00294

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [8]

According to International Patent Classification (IPC) or to both National Classification and IPC 4

A 61 B 5/02

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC 4	A 61 B 5/02, /03; G 01 D 5/26; G 01 L 1/24, 7/08, 9/00, 11/00
US Cl	73: 653, 655, 705, 715; 250: 227, 231

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

SE, NO, DK, FI Classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
A	US, A, 3 789 667 (PORTER ET AL) 5 February 1974	1, 5, 10
A	EP, A1, 0 092 505 (ASEA AB) 26 October 1983	1
A	DE, A1, 3 231 383 (BARTKOWIAK K.) 1 March 1984	
A	Patent Abstract of Japan, Vol. 9, No. 6, (P-326), abstract of JP 59-154 333, publ. 1984-09-03.	

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
1987-08-12	1987-08-25
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